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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/283,318 03/31/99 SMITH

J

HM12/0509

EXAMINER

JACK V SMITH  
PO BOX 5895  
ASHEVILLE NC 28813

FOLEY, S

ART UNIT

PAPER NUMBER

1648

*10*

DATE MAILED:

05/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.****Commissioner of Patents and Trademarks**

<b>Advisory Action</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/283,318	SMITH, JACK V.	
	Examiner Shanon A. Foley	Art Unit 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 4/24/01 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check only a) or b)]**

- a)  The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b)  In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search. (see NOTE below);
  - (b)  they raise the issue of new matter. (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

4.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
5.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
6.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
7.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8.  For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
 

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-4, 6, 7, 9, and 10.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

9.  The proposed drawing correction filed on \_\_\_\_\_ a) has b) has not been approved by the Examiner.
10.  Note the attached Information Disclosure Statement(s) ( PTO-1449) Paper No(s). \_\_\_\_\_.
11.  Other: see attached detailed action in response to arguments presented in the amendment.

Continuation of 3. NOTE: New issues include "microparticles" in claim 11, "beta-galactosidase enzyme conjugated to HIVantigen" in claim 16, enzymes and indicators in new claim 17; the claims also raise new issues of clarity.

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant has filed an amendment requesting cancelling claims 1-4, 6, 7, 9, and 10 and adding new claims 11-18.

This amendment has been denied entry, because the new claims involve new claim limitations that were not previously searched or considered. An amendment after final rejection can properly be denied entry if it raises new issues not previously considered.

Applicant disagrees with the reasons for not entering previous amendment B and specifically cites the location of support for the amendment in the original specification.

Applicant has failed to cite where the newly added issues can be found in the original claims. Although there is support found in the original specification for previous amendment B and new amendment C, the new limitations were not present in the claims examined before the final rejection and subsequently the new claim limitations were never searched or considered for patentability before the final rejection. Therefore, the proposed new claims will not be entered.

Applicant disagrees with the prior art cited against previously pending claims 1-4, 6, 9, and 10, and requests that the examiner produce prior art that uses the methods and formulas directed by the specification. It is the invention defined in the claims which is examined, not the methods and formulas disclosed in the specification.

Prosecution on the previously examined claims has been finalized. Newly added claims present new issues that will not be examined.

Applicant is welcome to continue prosecution at the Board of Appeals, or to re-open prosecution by filing a Continued Prosecution Application (CPA), or a Request for Continued Examination (RCE).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley  
May 8, 2001

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800  
1600